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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/024,197	12/21/2001	William Canfield	209794US0	4478

22850 7590 02/27/2003

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EXAMINER

SLOBODYANSKY, ELIZABETH

ART UNIT	PAPER NUMBER
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1652

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DATE MAILED: 02/27/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/024,197	CANFIELD, WILLIAM	
	Examiner	Art Unit	
	Elizabeth Slobodyansky	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-61 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-61 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____. | 6) <input type="checkbox"/> Other: _____. |

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DETAILED ACTION

Claims 1-61 are pending.

Election/Restriction

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-3, 9-11 (in part) and 4-7, drawn to a method of making a highly phosphorylated acid β -glucocerebrosidase (GBA) using hybrid GlcNAc phosphotransferase encoded by SEQ ID NO:1, classified in class 435, subclass 41.
- II. Claims 1-3, 9-11 (in part) and 8, drawn to a method of making a highly phosphorylated GBA using human GlcNAc phosphotransferase encoded by SEQ ID NO:3, classified in class 435, subclass 41.
- III. Claims 12-19, drawn to a highly phosphorylated GBA obtained by the method of claim 1, a pharmaceutical composition comprising thereof and methods of use thereof, classified in class 424, subclass 94.61.
- IV. Claims 20-25, 31-33 (in part) and 26-29, drawn to a method of making a highly phosphorylated GBA using hybrid GlcNAc phosphotransferase encoded by SEQ ID NO:1, classified in class 435, subclass 41.

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- V. Claims 20-25, 31-33 (in part) and 30, drawn to a method of making a highly phosphorylated GBA using human GlcNAc phosphotransferase encoded by SEQ ID NO:3, classified in class 435, subclass 41.
- VI. Claims 34-41, drawn to a highly phosphorylated GBA obtained by the method of claim 20, a pharmaceutical composition comprising thereof and methods of use thereof, classified in class 424, subclass 94.61.
- VII. Claims 42-51, drawn to a highly phosphorylated GBA encoded by SEQ ID NO:24, a pharmaceutical composition comprising thereof and methods of use thereof, classified in class 424, subclass 94.61.
- VIII. Claim 52, drawn to a method of making a highly phosphorylated GBA, classified in class 435, subclass 41.
- IX. Claims 53-61, drawn to a highly phosphorylated GBA obtained by the method of claim 52, a pharmaceutical composition comprising thereof and methods of use thereof, classified in class 424, subclass 94.61.

The inventions are distinct, each from the other because of the following reasons:

Inventions (I, II and III), (IV, V and VI) and (VIII and IX) each are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another

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and materially different process (MPEP § 806.05(f)). In the instant case a highly phosphorylated GBA can be obtained by methods of inventions I, II, IV, V or VIII. Methods of inventions I, II, IV, V and VIII are patentably distinct as employing different compounds such as proteins and DNAs and comprising different steps.

Methods of inventions (I and II) and (IV and V), respectively, are patentably distinct as methods using different compounds such as GlcNAc phosphotransferase encoded by SEQ ID NO:1 or 3 and DNAs of SEQ ID NO:1 or 3.

A highly phosphorylated GBAs of inventions III, VI, VII and IX are not necessarily have the same compositions and/or structures as being obtained by different modification methods.

A telephone call was made to Dr. Daniel Pereira on February 14, 2003 to request an oral election to the above restriction requirement, but did not result in an election being made.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim

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remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth Slobodyansky whose telephone number is (703) 306-3222. The examiner can normally be reached Monday through Friday from 9:30 AM to 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Ponnathapura Achutamurthy, can be reached at (703) 308-3804. The FAX phone number for Technology Center 1600 is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Center receptionist whose telephone number is (703) 308-0196.



Elizabeth Slobodyansky, PhD
Primary Examiner

February 24, 2003